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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,797	03/30/2004	Choong-Chin Liew	4231/2055M	4501

29933 7590 09/27/2007

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ART UNIT	**PAPER NUMBER**
1634	

MAIL DATE	DELIVERY MODE
09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,797	LIEW, CHOONG-CHIN	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAY WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communica
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53 and 63-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53, 63-73, and 75-76* is/are rejected.

7)☒ Claim(s) *74 and 77-87* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.12

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is written in response to applicant's papers received 6/26/07. Claims 53 and 63-87 are pending and addressed in this office action.

Claim Objections

2. Claims 74 and 77-87 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 72, 73, 75, 76, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72 recites the phrase "said control subjects not having said bladder cancer" in line 2 of the claim. This phrase lacks proper antecedent basis in the claim because the only previously recited controls are those that have bladder cancer.

Claim 73 recites the phrase "said healthy control subjects" in line 2 of the claim. This phrase lacks proper antecedent basis in the claim because the only previously recited controls are those that have bladder cancer or those that do not have bladder cancer. Controls that do not have bladder cancer are not equivalent to controls that are healthy and it is not clear if claim is

intending to further limit the controls or to simply refer to the controls that do not have bladder cancer.

Claim 75 recites the phrase "said control subjects not having said bladder cancer" in line 2 of the claim. This phrase lacks proper antecedent basis in the claim as the claim depends from claim 67 or 68 because these claims do not previously recite control subjects not having bladder cancer. Claim 67 does recite healthy control subjects, but the recitation in claim 75 "not having said bladder cancer" is broader than the reiteration in claim 67 and it is not clear if the recitation in claim 75 is actually meant to refer to the healthy control subjects recited in claim 67. There are only control subjects having said bladder cancer recited in claim 68.

Claim 76 recites "said healthy controls" in line 2 of the claim. This phrase lacks proper antecedent basis in the claim because the only previously recited controls are those that have bladder cancer (in claim 68) or "said control subjects not having said bladder cancer (in claim 72)."

5. Claims 53, 63-73, and 75-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of the invention

The invention is drawn to a method detecting a bladder cancer in a human test subject. The claims all include a step of determining the level RNA encoded by an insulin-like growth factor binding protein 7 (IGFBP7) gene in a blood sample obtained from said human and

comparing the level with a quantified level of RNA encoded by said gene in blood samples from control subjects having said bladder cancer. Some claims additionally include a comparison with a quantified level of RNA encoded by said gene in blood samples from control subjects that are healthy control subjects and/or control subjects not having said bladder cancer.

Some claims set forth that a determination of a statistically significant similarity between the test level and the level of control subjects having said bladder cancer "is indicative of said bladder cancer"

Some claims set additionally forth that a determination of a statistically difference between the test level and a quantified level of RNA from control subjects not having said bladder cancer and significant similarity between the test level and the level of control subjects having said bladder cancer "is indicative of said bladder cancer."

Some claims set additionally forth that a determination of a statistically difference between the test level and a quantified level of RNA from control subjects not having said bladder cancer and significant similarity between the test level and the level of control subjects having said bladder cancer "is indicative of said bladder cancer."

The nature of the invention requires the knowledge of a reliable association between comparing IGFBP7 expression and the indication that bladder cancer is present in a human. Further, the practice of the invention requires an understanding of how the presence of bladder cancer effects the level of IGFBP7 expression in human blood.

Scope of the claims

The claims are sufficiently broad so as to encompass detecting bladder cancer in general, or more specifically to encompass detecting the presence of a particular type or stage of bladder

cancer, since all of the claims now recite that the method is for detecting "a bladder cancer." Thus, the claims encompass methods where "a bladder cancer" is transitional cell carcinoma or squamous cell carcinoma or adenocarcinoma in particular, and the claims also encompass methods where "a bladder cancer" is a particular stage of bladder cancer. For example, reading claim 63- "a bladder cancer" could be "early stage bladder cancer" and the patients not having "said bladder cancer" as controls could be patients with "advanced stage bladder cancer" and so, the method would clearly encompass an indication that early stage bladder cancer is present relative to advanced stage bladder cancer. Applicants confirm their intent to encompass such an interpretation in their remarks on page 13 where they recite that the control subjects "have the bladder cancer of interest (ie the specific stage of bladder cancer that is being tested for) or they do not.

In addition, the "control subjects not having said bladder cancer" encompass patients with healthy patients, patients with some other disease, such as obesity or heart failure, patients with a particular stage of bladder cancer, etc.

The claims do not recite the level of statistical significance that is required to be reached, and so even with the requirement of statistical significance, the claims remain quite broad since no particular level is required. The phrase "statistically significant" describes a mathematical measure of a difference between groups, not a particular level of that difference which is acceptable. There is no universal accepted level of "statistically significant."

The claims are broad in scope because they encompass that ANY level and direction of difference in gene expression between the tested subject and the healthy controls or the controls not having said bladder cancer is indicative of said bladder cancer, if that difference is

statistically significant. That is, the claims do not set forth that one level should be higher or lower than the other, and further do not set forth how much of a "difference" between two individuals would be necessary to draw the conclusions set forth in the claims.

Teachings in the Specification/Examples

Regarding bladder cancer, the specification provides example 19 wherein gene expression profiles of blood samples from individuals having bladder cancer were compared with normal individuals, that is healthy patients. The specification teaches that 4,228 genes were identified as being differentially expressed, and regarding the instant claims, table 3J provides a list of these genes (Example 19). IGFBP7 is among the genes.

The tables list genes that were differentially expressed, but does not provide any further information. For example, the tables do not teach if the expression was higher or lower in bladder cancer patients versus controls.

The specification does not provide any guidance as to the level of "difference" that is sufficient (1 fold, 2 fold, etc) to result in a conclusion that bladder cancer is detected, nor does the specification provide any guidance as to the direction of the difference (higher or lower expression) that is expected to be observed for any single pairing of samples. The claims rely on comparisons between a test subject and the levels of quantified RNA from different types of controls, stating that particular observations of statistically significant differences or similarity between test and control can lead to different conclusions.

Notably, the specification also teaches that IGFBP7 is differentially expressed in the blood of patients who are obese versus healthy control patients (Example 15, Table 3F). In this

case as well, the specification is silent as to the nature of the difference in gene expression between patients with obesity and healthy controls.

The specification fails to provide information about an essential aspect of the invention, namely, the nature of the difference in expression that was observed between bladder cancer patients and healthy patients. Furthermore, though the specification teaches that this gene is differentially expressed in bladder cancer patients versus healthy patients, the specification teaches this is true for thousands of genes. There is no guidance or analysis of data in the specification to suggest that this gene in particular is sufficient to conclude that bladder cancer is present in a sample, as is instantly claimed. This information is essential to understanding and practicing the claimed invention because it is critical to knowing how to interpret a particular comparison result.

State of the Prior Art and Level of Unpredictability

Observing differences in expression between two populations is a highly unpredictable endeavor. The specification clearly exemplifies this for the case of IGFBP7. The specification teaches differential expression of this gene between populations of patients with bladder cancer and healthy controls. The specification also teaches that IGFBP7 is differentially expressed in the blood of patients who are obese versus healthy control patients (Example 15, Table 3F). So first, even if one carried out the claimed analysis on a test subject, and if one observed a level of expression, it is highly unpredictable how would one begin to know if that level of expression indicated bladder cancer, obesity, both, one but not the other, something in between or even some other condition or disorder for which the expression profile has not yet been determined. Additionally, Wang et al. (2003/0165949) teach that this gene is upregulated in leukemic cells

(see their Table 1, p. 22). Again, this adds another level of confusion when attempting to practice the claimed invention.

Further, IGFBP7 it is not listed in the tables for differentially expressed genes in patients who have both osteoarthritis and obesity versus normal controls. So, this exemplifies that a particular gene is not always differentially expressed in populations of patients having obesity versus healthy controls. Observing the differential expression result is population dependent- something about obese patients with osteoarthritis changes the observation. It is unknown and unpredictable whether this is also true for differential expression observations in bladder cancer patients. Furthermore, although IGFBP7 was not observed to be differentially expressed in any of the other examples in this specification, it is unknown and unpredictable whether it would be expressed in the blood of patients having other bladder diseases or other cancers or any other diseases which were not tested in the instant specification or diseases which were tested in the instant specification but in a different population of test subjects, and whether this expression would be different from levels of expression in healthy controls. A method for detection which relies on a comparison between expression in the blood of a test subject and control subjects requires the knowledge of this information in order to reliably "detect" bladder cancer, as set forth in the claims. The instant specification has not established that all difference, no matter the magnitude nor the direction, relative to any control subjects or even relative to a healthy control subject is indicative of bladder cancer. In fact, the specification shows that obese patients have a difference in this gene relative to healthy controls. It is not known under what circumstances the result observed in the instantly examined control and test populations would be repeatable, as the results have not been validated. But even if one were to obtain the same result, it would be

unknown because applicant did not disclose the magnitude of difference in expression between bladder cancer patients or controls, nor did applicant disclose the direction of variation. All of these inquiries are particularly important in this case since the specification is silent as to which differential expression observations would be sufficient to detect the presence of bladder cancer.

In the post-filing art, Osman et al. provide an analysis which includes microarray hybridization of test and control isolated from total cellular RNA where the test is patients with bladder cancer and the control is healthy individuals (Osman et al. Clinical Cancer Research 2006; 12(11) 3371-3380). Osman et al. teach that 1,088 genes were differentially expressed, and that one of these was IGFBP7 (Results). Osman et al. teach, in the post filing date art, what the instant specification fails to teach, that is that this gene was overexpressed in bladder cancer patients compared with healthy controls. Osman et al. suggest the use of this gene as part of a panel of expressed genes for detecting bladder cancer, but they do not teach that this gene alone is sufficient to detect bladder cancer. Even in view of this disclosure, Osman et al. teach that their study has several limitations including that "the expression profiles may represent the activation of specific immunologic response to the presence of bladder tumors, and that the profiles identified in this study may be intrinsic to the cohort of patients evaluated in this study (p. 3379)." The field remains highly unpredictable years after the filing of the instant application, even with the significantly more guidance given in this post-filing date reference.

Neither the specification nor the claims set forth a threshold of difference between an individual's expression and the control expression of IGFBP7 in the blood that would be sufficient to conclude that the difference in gene expression between a test individual and any type control group is "indicative of" any of the recited bladder cancer. Because the claims

encompass any level of altered gene expression, it is relevant to point out that the art of Cheung et al (2003) teaches that there is natural variation in gene expression among different individuals. The reference teaches an assessment of natural variation of gene expression in lymphoblastoid cells in humans, and analyzes the variation of expression data among individuals and within individuals (replicates) (p.422, last paragraph; Fig 1). The data indicates that, for example, expression of ACTG2 in 35 individuals varied by a factor of 17; and that in expression of the 40 genes with the highest variance ratios, the highest and lowest values differed by a factor of 2.4 or greater (Fig 3). It is thus unpredictable as to whether or not any level of altered gene expression is indicative of a bladder cancer or the absence of bladder cancer.

The unpredictability of correlating gene expression level to any phenotypic quality is taught in the post-filing art of Wu (2001). Wu teaches that gene expression data, such as microarray data, must be interpreted in the context of other biological knowledge, involving various types of 'post genomics' informatics, including gene networks, gene pathways, and gene ontologies (p.53, left col.). The reference indicates that many factors may be influential to the outcome of data analysis, and teaches that expression data can be interpreted in many ways. The conclusions that can be drawn from a given set of data depend heavily on the particular choice of data analysis. Much of the data analysis depends on such low-level considerations as normalization and such basic assumptions as normality (p.63 - Discussion). The art of Newton et al (2001) further teaches the difficulty in applying gene expression results. Newton et al. teaches that a basic statistical problem is determining when the measured differential expression is likely to reflect a real biological shift in gene expression, and replication of data is critical to validation (p.38, third full paragraph). There is no replication of data in the instant specification.

Quantity of Experimentation

The instant specification does not provide enabling support for the practice of a single embodiment within the claimed invention. In particular, the specification does not provide adequate guidance to appraise one of ordinary skill in the art as to what levels of IGFBP7 gene expression must be observed to successfully conclude that bladder cancer is present. Further, although the specification teaches there are differences in IGFBP7 levels in a bladder cancer population versus a control patient population, the specification is silent as to the nature of the "difference" in magnitude or direction. Thus, given the lack of teaching in the specification and the highly unpredictable nature of the technology, an extensive amount of work would be required to practice the claimed invention.

In order to practice the claimed invention, one would have to undertake an extensive amount of experimentation in a highly unpredictable technology area. One would begin by trying to reproduce the results observed in the instant specification to determine if there is a relative upregulation or downregulation of IGFBP7 in bladder cancer patients versus healthy control patients, as the specification does not even provide this minimal guidance. Without this knowledge one would not even begin to know how to interpret any results obtained in practicing the claimed methods. For example, consider the comparison of a test result and a control population of healthy individuals. How different from the average level of expression of healthy individuals would the test result have to be to indicate bladder cancer? Would any difference, up or down regulation be indicative of bladder cancer? Or could one indicate bladder cancer and one obesity? Is IGFBP7 expressed in the blood of individuals with a disease other than obesity and bladder cancer? Is this expression also diagnostic of other cancer or other diseases of the

bladder or other disorders entirely unrelated to bladder cancer? In order to reliably use a method for detecting bladder cancer, one would first have to answer at least these questions. One would also, however, have to carry out this testing for validation, for it is possible that the result observed in the instant specification is intrinsic to the cohort of patients evaluated in applicant's study. Further, one would have to undertake experimentation to determine difference thresholds required to determine that a patient has or does not have a disease.

As discussed, this art area is highly unpredictable.

Conclusion

The claims include methods which encompass the detection in blood of the expression of IGFBP7 in a test subject and comparing this expression to control subjects, wherein the comparison itself "is indicative of bladder cancer." The identification of gene differential expression/disease indication relationships is a highly unpredictable endeavor, requiring extensive experimentation. The specification provides minimal guidance. In light of the factors discussed, therefore, it is concluded that it would require undue experimentation to practice the claimed invention.

Conclusion

Response to Remarks

The rejections have been modified to address the amended claims and to address the newly added claims. Applicant states in their summary of the nature of the invention and the scope of the claims that the claimed methods "do not permit 'any level and direction of difference in gene expression to be indicative of disease.'" The claims have been amended to require that statistically significant similarity between the test and control subjects having said

bladder cancer, and in some also cases statistically significant difference between the test subject level and controls not having said bladder cancer or healthy controls, but still the claims are sufficiently broad so as to encompass any level or direction of difference, for the claims that recite the difference, provided the level rises to the level of "statistically significant." Further, the claims do not recite the level of statistical significance that is required to be reached, and so even with the requirement of statistical significance, the claims remain quite broad since no particular level is required.

Applicant argues that the specification is enabling for the claimed invention without disclosing the direction or the level of the difference that exists between patients having bladder cancer and individuals not having bladder cancer, and that applicant's teaching in Example 19, Figure 17 and Table 3J is sufficient. To be clear, in this example, patients having bladder cancer (any type of bladder cancer p.78, line 9 and following) were compared to patients identified as unaffected by any disease (p. 78, line 18). So the "control" patients are correctly identified as "not having bladder cancer" but more specifically they are control patients not having any disease. However, this is an unpredictable technology, as discussed in the rejection. So, simply establishing that one has the same level as a particular control group of patients "having said bladder cancer" is not sufficient to enable on to "detect" bladder cancer, as the claims set forth. The specification demonstrates that this particular gene is also differentially expressed relative to a different disease (obesity), and does not disclose the level of expression in either case. So, it is not known, and unknowable from the specification if the level of expression in obesity is the same as that for bladder cancer patients. Likewise, as pointed out in the rejection this gene is differentially expressed in blood of patients with leukemia, and so it is not known if this level is

the same or different as those patients with bladder cancer. The claims recite that they are methods for "**detecting**" bladder cancer, and so in order to detect the disease one must be able to put the result into a larger context. The claims are not limited to comparison between patients having bladder cancer and not having bladder cancer, they are broadly drawn and recite control subjects having "a bladder cancer" and control subjects not having "said bladder cancer." There is not even a showing in the specification that the levels of this gene differ in different stages of bladder cancer, yet applicant's claims encompass methods wherein "said bladder cancer" is a particular stage of bladder cancer and comparison to a level of the gene expression from a different stage of the cancer.

Applicant further argues on page 14 of the response that it does not require undue experimentation to determine the inherent direction or level of the statistically significant differential expression required, give the widely established and validated analytical tools for analyzing gene expression levels. This attorney argument is not supported by evidence on the record, for example showing an independent confirmation of the result given in the specification. The rejection discusses at length the art established need for replication in order to enable the use or a gene expression marker as a diagnostic tool, and indeed cites a post filing date reference where this is suggested for the gene that is the subject of the claimed invention. In the background of the unpredictable nature of the claimed invention, the lack of disclosure regarding the direction of the expression change and the level of the difference in bladder cancers and other diseases weighs heavily in the factors for determining that the claimed invention would require undue experimentation to practice.

To support their argument that observing differences in gene expression between two populations is predictable, applicant relies heavily on data provided in post filing research article Osman et al. Applicant's specification must be enabling at the time of filing of the application, and further, peer reviewed literature cannot replace evidence on the record to overcome a rejection for lack of enablement. Based on the disclosed fact pattern in the instant specification, one could not extrapolate that IGFBP7 expression is sufficient to "detect" bladder cancer, as set forth in the claims. On cannot readily extrapolate whether or not the level of IGFBP7 is the same or different in bladder cancer and other diseases such as leukemia and obesity. If the levels are the same, it would not be sufficient to show that IGFBP7 expression is the same as a patient with bladder in order to detect bladder cancer. One cannot readily extrapolate that the observation made in the specification is the same universally and not cohort specific. One cannot readily extrapolate one could successfully differentiate different types or stages of bladder cancer based on the disclosed data.

Applicants state that the fact that Applicant discloses that IGFBP7 is also differentially expressed in obesity is not detrimental to either the value or enablement of the use of the gene as a biomarker which is indicative of bladder cancer, since IGFBP7 was not identified as a differentially expressed marker in many of the other diseases. However, of all possible diseases, only a small subset was tested, and only one type of cancer or bladder disease. Applicant refers to the specificity of IGFBP7 as confirmed by Osman et al., but this reference cannot be relied upon as evidence to demonstrate the enablement of the claimed invention because it is not in proper declaration form (MPEP 716.02(g)). Furthermore, applicant is reminded that all evidence traversing rejections, including affidavits of declarations must be timely filed (MPEP 716.01).

Applicant states that it would be highly unlikely that the level and/or direction of expression in patients with bladder cancer would be statistically similar to the level of expression in patients with other non-related diseases. This is not supported by evidence on the record, and amounts to an attorney argument. Neither the specification nor evidence on the record, however, establish IGFBP7 levels for even "related" diseases. The claims encompass even staging of bladder cancer, as previously discussed in this office action, but the specification makes no showing that IGFBP7 levels differ among individuals with different types or stages of bladder cancer.

Applicant undertakes a discussion of the meaning of "indication" pointing out that it is not equated with "diagnosis." The instant claims set forth that they are a method for detecting bladder cancer. Broadly and reasonable interpreted, "detecting a bladder cancer" means determining that it is there, and so the claims must be so enabled.

Regarding the question of whether or not IGFBP7 is sufficient to conclude that bladder cancer is present in a sample, applicant states that it is only a result of the USPTO's policy regarding restriction requirements that the Applicant has been forced to narrow the claims to a specific gene or set of genes. This argument is irrelevant to the issue of enablement. It is additionally noted there was no requirement that applicant cancel linking claims which were present in the original claim set and generic to any possible gene or combination of genes from the instant application. Second, there was no requirement that only a combination of a single gene method be elected. These were decisions made by applicant and not the office.

Applicant again points out that Osman et al. demonstrates that the elected gene can be used in combination with other genes and is therefore confirmation that the gene is indicative of

bladder cancer. This is not confirmation that the gene can, alone, detect bladder cancer, as claimed, it is a showing that the gene can be used with other genes to detect bladder cancer.

Applicant states that Osman's discussion regarding the "outside" possibility that the cohort of bladder cancer patients tested may not be representative of bladder cancer patients in general does not diminish the enablement of the claimed methods. Applicant makes this statement after pointing out that the examiner cited a reference in a parent application as showing a particular change in gene expression is indicative of disease. That reference is enabled for what it teaches, that is, the relationship it demonstrates in the particular fact pattern of the reference. The showing in Nagai et al. indicates the gene is indicative of disease for the cohort tested, not for any possible group of people. Osman's statement is direct and does indeed point to the importance of replication before a particular relationship can be considered as valid within this technology.

The rejection is maintained and updated to address the amended and newly filed claims.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Juliet C. Switzer
Primary Examiner
Art Unit 1634

September 24, 2007